

**REMARKS****Status of the Claims**

Claims 1, 12, 21-23, 31-34, 37-42, 44-48, 50-55, 58-65 and 67-72 were currently pending. Claims 1, 12, 21-22, 31-34, 37-42, 44-48, 50-55, 58-65 and 67-72 are currently rejected. Claims 1, 31, 39, 45, 50, 60, and 68 have been amended to change the phrase “no more than one conservative amino acid substitution” to “a single conservative amino acid substitution.” Support for the amendment can be found in paragraph [0018] as filed, as discussed further below.

After entry of the amendment, claims 1, 12, 21-23, 31-34, 37-42, 44-48, 50-55, 58-65 and 67-72 will be pending.

This application pertains to compositions and assays for sodium and lithium ions using ion-sensitive enzymes. In particular, the ion-sensitive enzyme is a chimeric protein comprising a specific bacterial leader sequence, a 3'(2'), 5"-bisphosphate nucleotidase of SEQ ID NO:2 (or having a single conservative amino acid substitution and at least 90% of the bisphosphonate activity of SEQ ID NO:2); and a fragment comprising the sequence of SEQ ID NO:3. The bisphosphonate activity is the activity of forming inorganic phosphate and AMP from adenosine 5' biphosphate. (See paragraph [0043] of the specification).

The claims were not rejected over the prior art.

Entry of the amendment and reconsideration in view of the following comments is respectfully requested. With respect to all amendments, Applicants have not dedicated or abandoned any unclaimed subject matter and moreover have not acquiesced to any rejections and/or objections made by the Patent Office. Applicants expressly reserve the right to pursue prosecution of any presently excluded subject matter or claim embodiments in one or more future continuation and/or divisional application(s).

Applicants have carefully considered the points raised in the Office Action and believe that the Examiner's concerns have been addressed as described herein, thereby placing this case into condition for allowance.

#### Claim 23

Claim 23 was not rejected or objected to in the previous Office Action, and accordingly, Applicants submit that this claim should have been indicated as allowable.

#### The Rejection Under 35 U.S.C. § 112, First Paragraph, Written Description

The Office rejected claims 1, 12, 21-22, 31-34, 37-42, 44-48, 50-55, 58-65 and 67-72 for allegedly containing new matter. The Office stated that the phrase "having no more than one conservative amino acid substitution" is not supported by the specification.

Applicants respectfully traverse this rejection.

To satisfy the written description requirement, a patent application must describe the invention in sufficient detail that one of skill in the relevant art could conclude that the inventor was in possession of the claimed invention at the time the application was filed. See *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, (Fed. Cir. 1991). The Federal Circuit in *Union Oil of California*, made it clear that an applicant need not precisely recite each and every element of a claim limitation in the specification in order to satisfy the written description requirement. See *Union Oil of Cal. v. Atlantic Richfield Co.*, 208 F.3d 989 (Fed. Cir. 2000).

Without acquiescing to the rejection, Applicants have changed the phrase "no more than one conservative amino acid substitution" to "a single conservative amino acid substitution."

SEQ ID NO:2 is the Hal2p protein. This protein was known in the art at the time the application was filed, as evidenced by paragraph [0040]. The Hal2p protein has 3'(2'),5'-biphosphate nucleotidase activity. See paragraph [0018]. Paragraph [0018] of the specification as filed states that "a 3'(2'),5'-biphosphate nucleotidase can include conservative amino acid

substitutions that do not substantially alter its activity” and further states that “single amino acid substitutions in non-essential regions of a polypeptide do not substantially alter biological activity.” Accordingly, a person of skill in the art reading the specification would understand it to clearly and unambiguously disclose single amino acid substitutions of the Hal2p protein, and understand that those substitutions can be conservative amino acid substitutions.

In light of the foregoing discussion, Applicants respectfully submit that the specification, provides sufficient disclosure to convey to a person skilled in the art that Applicants were in possession of the claimed invention. Accordingly, Applicants respectfully submit that this written description rejection under 35 U.S.C. § 112, first paragraph may properly be withdrawn.

**CONCLUSION**

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket No. 466992001100. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

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By: / Elizabeth Cary Miller / \_\_\_\_\_  
Elizabeth Cary Miller  
Registration No.: 54,708  
MORRISON & FOERSTER LLP  
12531 High Bluff Drive, Suite 100  
San Diego, California 92130-2040  
(858) 314-7717